November 4, 2022

Penumbra, Inc.
Sindokht Soltanzadeh
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

Re: K221822
Trade/Device Name: BENCHMARK BMX81 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: October 7, 2022
Received: October 11, 2022

Dear Sindokht Soltanzadeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221822

Device Name
BENCHMARK BMX81 Access System

Indications for Use *(Describe)*
The BENCHMARK BMX81 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the subject BENCHMARK BMX81 Access System.

1.1 Submitter

Penumbra, Inc.
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Date of Preparation:

November 2, 2022

1.2 Subject Device

BENCHMARK BMX81 Access System

Regulatory Class: II
Classification Panel: Neurology
Classification Name: Catheter, Percutaneous, Neurovasculature
Regulation Number: 21 CFR 870.1250
Product Code: QJP, DQY

1.3 Predicate/Reference Devices

510(k) Number	Name of Device
Predicate Device	
K212838	Benchmark Intracranial Access System
Reference Device	
K201271	Benchmark BMX96 System

1.4 Device Description

The BENCHMARK BMX81 Access System is a three-component system comprised of the BMX81 Delivery Catheter, Penumbra Select Catheter, and a Dilator. The BMX81 Delivery Catheter can be used individually with a 0.038 in [0.97 mm] guidewire or together with the Penumbra Select Catheter to access the desired anatomy.

BMX81 Delivery Catheter:

The BMX81 Delivery Catheter is a single lumen, variable stiffness catheter with a radiopaque markerband on the distal end and a Luer hub on the proximal end. The BMX81 Delivery Catheter dimensions are included on the individual device label. The BMX81 Delivery Catheter is compatible with introducer sheaths appropriately sized for the outer diameter of BMX81 Delivery Catheter. The BMX81 Delivery Catheter has a hydrophilic coating on the distal segment of the catheter shaft. The hydrophilic coating length is 18 cm.

Penumbra Select Catheter:

The Penumbra Select Catheter is a single lumen, braid-reinforced, variable stiffness 5F catheter with a radiopaque distal end and a Luer hub on the proximal end. The Penumbra Select Catheter is available in tip shapes (SIM, H1, or BER). The Penumbra Select Catheter tip shape and dimensions are included on the individual device label. The Penumbra Select Catheter is compatible with the BMX81 Delivery Catheter.

Dilator:

The Dilator is a single lumen, radiopaque catheter with a tapered distal end and a Luer hub on the proximal end. The Dilator is compatible with the BMX81 Delivery Catheter. The Dilator facilitates the percutaneous entry of the BMX81 Delivery Catheter by forming an atraumatic transition from the skin through the subcutaneous tissue to the vessel.

The BENCHMARK BMX81 Access System is a single-use, ethylene oxide (EO) sterilized system.

The BENCHMARK BMX81 Access System should only be used by physicians who have received appropriate training in interventional techniques.

1.5 Indications For Use

The BENCHMARK BMX81 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

1.6 Comparison of Technological Characteristics with the Predicate/Reference Devices

The subject device BENCHMARK BMX81 Access System has similar technological characteristics to the previously cleared predicate and reference devices. At a high level, the subject and predicate and reference devices are based on the following same technological elements:

- Principles of Operation
- Delivery Catheter materials
- Delivery Catheter tip shapes
- Dilator materials and inner diameter (ID)
- Neuron 5F Select Catheter (K083125)*
- Accessories
- Sterilization method (EO)

*Note: The Penumbra Select Catheter included in the subject BENCHMARK BMX81 Access System is identical to the Neuron 5F Select Catheter (K083125) and identical to the Select Catheter included in the predicate Benchmark Intracranial Access System (K212838).

The following technological differences exist between the subject and predicate and reference devices:

- Delivery Catheter dimensions (inner diameter (ID), outer diameter (OD), Effective Lengths, Distal Flexible length)
- Hydrophilic coating
- Dilator OD and effective length
- Packaging pouch material
- Shelf-life

1.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Design Verification

- Biocompatibility
- Shelf Life
- Sterilization
- Packaging

The subject device met all established requirements.

1.7.1 Performance Testing

- Design Verification
    - Visual and Dimensional Inspection
    - Particulate Testing
    - Friction Testing
    - Simulated Use Testing
    - Radiopacity Testing/Markerband Visibility
    - Hub Air Aspiration Testing
    - Burst Pressure Testing
    - Tensile and Elongation Testing
    - Corrosion Testing
    - Liquid Leakage Testing
    - Kink Resistance
    - Torsion Testing in Simulated Use Model
    - Catheter Tip Stiffness Testing
- Shelf Life
- Packaging
- Sterilization in accordance with ISO 11135+A1 and ISO 10993-7

1.7.2 Biocompatibility

The biocompatibility evaluation for BENCHMARK BMX81 Access System was conducted in accordance with ISO 10993-1, USP standards, and FDA Good Laboratory Practices (GLP) as recognized by FDA. The battery of testing included the following tests:

Tests	Results – BMX81 Delivery Catheter	Results – Dilator	Conclusions
Cytotoxicity: MEM Elution (10993-5)	Grade = 0 (Reactivity None)	Grade = 0 (Reactivity None)	Pass Non-cytotoxic
Sensitization:	NS Extract: Grade = 0	NS Extract: Grade = 0	Pass Non-sensitizing

Tests	Results – BMX81 Delivery Catheter	Results – Dilator	Conclusions
Magnusson-Kligman Method (10993-10)	SSO Extract: Grade = 0	SSO Extract: Grade = 0	
Irritation: Intracutaneous Reactivity (10993-10, 10993-23)	NS Extract Difference = 0.0	NS Extract Difference = 0.0	Pass Non-irritating
	SSO Extract Difference = 1.0	SSO Extract Difference = 0.1	
Systemic Toxicity: Acute Systemic Injection (10993-11)	No evidence of systemic toxicity from sample extracts (both NS and SSO extracts). That is: • No deaths • No signs consistent with toxicity • No weight loss > 10%	No evidence of systemic toxicity from sample extracts (both NS and SSO extracts). That is: • No deaths • No signs consistent with toxicity • No weight loss > 10%	Pass Non-toxic
Systemic Toxicity: Material Mediated Pyrogen (10993-11)	Non-pyrogenic: no single animal had an individual rise in body temperature ≥ 0.5 °C	Non-pyrogenic: no single animal had an individual rise in body temperature ≥ 0.5 °C	Pass Non-pyrogenic
Hemocompatibility: *In-vitro* Thrombogenicity (10993-4)	**Assay #1:** Thromboresistant **Assay #2:** Thromboresistant **Assay #3:** Thromboresistant	**Assay #1:** Thromboresistant **Assay #2:** Thromboresistant **Assay #3:** Thromboresistant	Pass Non-thrombogenic
Hemocompatibility: Prothrombin Time (PT) (10993-4)	Test article coagulation times are statistically similar to predicate	Test article coagulation times are statistically similar to predicate	Pass Hemocompatible
Hemocompatibility: Partial Thromboplastin Time (PTT) (10993-4)	Test article coagulation times are acceptable	Test article coagulation times are acceptable	Pass Hemocompatible
Hemocompatibility: Complement Activation (10993-4)	Based on Tukey test, test article concentrations of SC5b-9 are statistically similar to predicate at exposure time point	Test article concentrations of SC5b-9 are statistically similar to predicate at exposure time point	Pass Hemocompatible
Hemocompatibility: Hemolysis, indirect contact (10993-4)	Hemolytic Index = 0.00%	Hemolytic Index = 0.00%	Pass Non-hemolytic
Hemocompatibility: Hemolysis, direct contact	Hemolytic Index = 0.21%	Hemolytic Index = 0.00%	Pass Non-hemolytic

Tests	Results – BMX81 Delivery Catheter	Results – Dilator	Conclusions
(10993-4)			

Biocompatibility test results demonstrate biological safety per ISO 10993-1 and USP requirements.

1.7.3 Performance Data – Animal, Clinical

No animal or clinical studies were conducted because bench testing was determined sufficient for verification and validation purposes.

1.8 Conclusions

The subject BENCHMARK BMX81 Access System is substantially equivalent to the predicate device Benchmark Intracranial Access System. The subject device has the same indications for use as the predicate device. The device testing described in the 510(k) Summary demonstrates that the subject device is substantially equivalent to the predicate device in regard to intended use, operating principle, design concept, fundamental technology and device performance. The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness.